DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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June 25, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Keith A. Vander Dussen
Partner
Countyline Dairy II
160 E. Jackson Road
Lake Arthur, New Mexico 88253

PURGED

Ref. #: DEN-01-38

Dear Mr. Vander Dussen:

Consumer Safety Officer Betty K. Baxter conducted an investigation at your dairy farm located in Lake Arthur, New Mexico on April 18 & 19, 2001. The inspection confirmed that you offered animals for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On June 8, 2000, February 12, 2001, February 13, 2001 and again on March 9, 2001, you offered 4 cows for slaughter as human food to [redacted] All of those cows, identified as USDA case number 99-0263-NM, were found with illegal levels of drug residues.

Specifically, USDA analysis of tissue samples collected from cow #492, on February 12, 2001, identified the presence of penicillin residue of 0.26 ppm in the kidney, and sulfadimethoxine residue of 0.15 ppm in the liver and 0.17 ppm in the muscle. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of beef cows in Title 21 Code of Federal Regulations Part 556.510 (21 CFR 556.510). A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of beef cows in 21 CFR 556.640.

USDA analysis of tissue samples collected from cow #1930, on February 13, 2001, identified the presence of penicillin residue of 0.26 ppm in the kidney, 0.15 ppm in the liver and 0.08 ppm in the muscle; and sulfadimethoxine residue of 4.10 ppm in the liver and 1.87 ppm in the muscle.

USDA analysis of tissue samples collected from cow #1563, on March 9, 2001, identified the presence of penicillin residue of 0.56 ppm in the kidney and 0.08 ppm in the liver; and sulfadimethoxine residue of 0.15 ppm in the liver and 0.14 ppm in the muscle.

USDA analysis of tissue samples collected from cow #839 on June 8, 2000, identified the presence of penicillin residue of 0.28 ppm in the liver and 0.21 ppm in the muscle.

Following our April, 2001 inspection, we learned of yet another illegal penicillin residue reported as USDA Sample #408448, involving cow #16110.

Our investigation revealed the use of Agrilabs Agri-Cillin Penicillin G Procaine Suspension U.S.P., Fort Dodge Animal Health Hetacin-K (Hetacillin Potassium) and Pfizer Animal Health Albon (sulfadimethoxine) Boluses. The presence of these drugs at the levels found in edible tissue from these animals causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are inadequate to prevent medicated animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

PURGED

Thomas A. Allison
District Director